ONLINE-ONLY APPENDIX: LIST OF INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA

[1] Male subjects between the ages of 35 and 70 years, inclusive, with Type 2 diabetes mellitus as defined by the American Diabetes Association (Diabetes care, Vol. 21: S5-S19, 1998) for more than one year.
[2] Subjects must have Body Mass Index (BMI) < 36 kg/m².
[3] Stable glycemic control (Hb_{A1C} <11%).
[4] Subjects must be off all oral hypoglycemic agents 24 hours prior to each study dosing day and off any investigational drug for at least four weeks.
[5] Subjects must refrain from strenuous physical activity beginning 72 hours prior to admission and through the duration of the study.
[6] Subjects must be willing and able to be confined to the Clinical Research Unit as required by the protocol.
[7] Subjects must be willing and able to provide written informed consent.

EXCLUSION CRITERIA

[1] History or presence of clinically significant cardiovascular, respiratory, hepatic, renal, gastrointestinal, neurological or infectious disorders capable of altering the absorption, metabolism or elimination of drugs, or of constituting a risk factor when taking the study medication.
[2] Subjects with gastroparesis, orthostatic hypotension and hypoglycemia unawareness (autonomic neuropathy).
[3] Subjects with "brittle" diabetes or predisposition to severe hypoglycemia, e.g., 2 or more serious hypoglycemic episodes (requiring another's assistance) within the past year, or any hospitalization or emergency room visit due to poor diabetic control within the past 6 months.
[4] Evidence of significant active hematological disease and/or cumulative blood donation of 1 unit (500 mL) or more including blood drawn during clinical trials in the last 3 months.
[5] Positive hepatitis B (hepatitis B surface antigen) and/or hepatitis C (hepatitis C antibody) serology.
[6] Positive HIV serology.
[7] Evidence of significant active neuropsychiatric disease.
[8] Known allergy to human insulin excipients contained in these products.
[9] Regular alcohol intake greater than 28 units*/week (male), or 21 units/week (female), or subjects unwilling to stop alcohol for the duration of the study (* 1 unit = 8 g ethanol, ¼ liter of beer or 1 glass wine or 1 measure of spirits).
[10] Intake of any drug which in the evaluation of the investigator may interfere with the interpretation of trial results or are known to cause clinically relevant interference with insulin action, glucose utilisation or recovery from hypoglycemia.
[11] Treatment with s.c. insulin injections.
[12] Investigators, site personnel directly affiliated with this study, and their immediate families. Immediate family is defined as a spouse, parent, child or sibling, whether biological or legally adopted.
[13] Have any other condition (including drug abuse, alcohol abuse, or psychiatric disorder) that, in the opinion of the investigator, precludes the patient from following and completing the protocol.